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Research Article

ASSAY OF IRBESARTAN BY EXTRACTIVE SPECTROPHOTOMETRY

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ABSTRACT

Two simple and sensitive extractive spectrophotometric methods have been developed for the estimation of Irbesartan (IST) in pure and pharmaceutical dosage forms. These methods are based on the formation of ion-pair complexes of the drug with acidic dyes Solochrome black T (SBT: λmax 520nm) and Solochrome black Blue (SBB) : λmax 540 nm). The absorbance of the chloroform extracts is measured against the corresponding reagent blanks. These methods have been statistically evaluated and found to be precise and accurate.

Keywords: Irbesartan, Assay, Extractive Spectrophotometry.

INTRODUCTION

Irbesartan (IST) is chemically called 1,3-Diazaspiro[4.4]non-1-en-4-one,2-butyl-3-[[2¢-(1H-tetrazol-5-yl)[1,1¢-biphenyl]-4-yl]methyl]-.2-Butyl-3-[p-(o-1H-tetrazol)benzyl] 5ylphenyl-1,3-diazaspiro[4.4]non-1-en-4-one [138402-11-6] .It is official in US Pharmacopoeia. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination in its pure form and pharmaceutical formulations. In the present investigation two simple and sensitive extractive spectrophotometric methods have been developed for the determination of IST. The developed methods involve the formation of coloured chloroform extractable complexes with SBT and SBB Extractable complexes showed absorption maximum at 520 and 540 nm respectively. Beers law is obeyed in the concentration ranges of 10-30µg/ml and 10-30µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies.

EXPERIMENTAL

Preparation of reagents

1. Solochrome Black T Solution: 0.5 g of SBT dye was dissolved in 100 ml of distilled water.
2. Solochrome Black Blue Solution: 0.5 g of SBB dye was dissolved in 100 ml ofdistilled water.
3. Acid phthalate buffer pH 2.2 [I.P].
4. Standard drug solution: About 100mg of Irbesartan was accurately weighed and dissolved in 100 ml of water to obtain a stock solution of 1 mg/ml. This solution was further diluted with distilled water to get working standard solution of 100 µg/ml.

ASSAY PROCEDURES

Method A

Aliquots of working standard solution of IST ranging from 1-3 ml were transferred into a series of 125 ml separating funnels. To these 1 ml of buffer solution (pH 2.2) and 1 ml of SBT dye were added. The total volume of aqueous phase was adjusted to 10 ml with distilled water and 10 ml of chloroform was added. The contents were

shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the Pink colored chromogen was measured at 520 nm against reagent blank and the amount of IST present in the sample solution was computed from its calibration curve.

Method B

Aliquots of working standard solution of IST ranging from 1-3 ml were transferred into a series of 125 ml separating funnels. To these 2 ml of SBB dye was added. The total volume of aqueous phase was adjusted to 10 ml with distilled water and 10 ml of chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the Bluish-pink colored chromogen was measured at 540 nm against reagent blank and the amount of IST present in the sample solution was computed from its calibration curve .

RESULTS AND DISCUSSION

The optical characteristics such as beers law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, percent range of error(0.05 and 0.01 confidence limits) were calculated for both the methods and results are summarized in Table 1. The values obtained for the determination of IST in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interference in the proposed methods.

Table 1: Optical characteristics, precision and accuracy of the proposed method

Parameters	Method A	Method B
λ_{max} (nm)	520	540
Beer's law limit(µg/mL)	10-30	10-30
Sandell's sensitivity(µg/cm^2/0.001 abs. unit	0.0331	0.0099
Molar absorptivity(litre.mole^{-1}.cm^{-1})	5.53×10^5	1.988×10^6
Regression equation(Y*)		
Slope(b)	0.0239	0.1156
Intercept(a)	0.073	0.0286
Correlation coefficient(r)	0.9993	0.9995
%Relative standard deviation**	1.062	1.19
%Range of error		
0.05 significance level	0.892	0.984
0.01 significance level	1.323	1.420

*Y = a + bx, where 'Y' is the absorbance and x is the concentration Irbesartan in µg/mL
**For six replicates

Table 2: Estimation of Irbesartan in Pharmaceutical Formulations

Formulations (Tablets)	Labelled amount(mg)	Amount found* by proposed method		% recovery** by proposed method	
		Method A	Method B	Method A	Method B
Tablet 1	5	4.83	4.85	99.15	99.35
Tablet 2	5	4.85	4.96	99.26	99.46
Tablet 3	10	9.76	9.85	98.85	99.35
Tablet 4	10	9.85	9.95	99.16	99.46

***** Average of six determinations
******Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

CONCLUSION

The proposed methods are applicable for the assay of drug IST and have an advantage of wider range under Beers law limits. The proposed methods are simple, selective and reproducible and can be used in the routine determination of IST in pure form and formulations with reasonable precision and accuracy.

REFERENCES

1. The Merck Index, 13th edition, Merck Research laboratories, White House station, NJ, 2001, pg.1041.
2. Sunil K Dubey, Anil Patni, E-Journal of Chemistry, 2009, 6(4), 1063-1070
3. Seshagiri rao JVLN, Srinivasa babu Y and K.P.R.Chowdary. Acta Ciencia Indica. 2003;XXIXC(3):207.
4. Devala Rao G, Ratna Kumari K and Vijaya Kumari S. Acta Ciencia Indica. 2009;XXXV(2):281.
5. Devala Rao G and Vijaya Saradhi S. Acta Ciencia Indica. 2009;XXXVC(1):101.
6. Chitra K, Sujatha K and Ghosh A. Indian Drugs. 2004;41(8):478-481.